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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,530	LEGRAIN ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1,3-5,7,8,12,14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,6,9-11,13 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is a reply to the Paper Filed 26 April 2004 in response to the Non-Final Office Action mailed 22 October 2003. Claims 1, 3-5, 7, 8, 12, 14 and 15 were withdrawn from consideration and claims 2, 6, 9-11 and 13 were considered in the 22 October Office Action. Claims 2, 6, 9-11 and 13 were amended and claims 16-20 were added in the 26 April Paper. Claims 1-20 are pending and claims 2, 6, 9-11, 13 and 16-20 are under consideration.

Response to Amendment

Specification

Objection to the disclosure as containing an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of the amendments thereto.

Claim Rejections - 35 USC § 112

Rejection of claim 9 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claims.

Claims 10 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and herein below in the response to arguments.

Claim 13 stands rejected and newly added claims 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Rejection of claims 2, 9-11 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 102

Claims 6, 9-11 and 13 stand rejected and claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Cenciarelli *et al.* (1999) *Curr. Biol.* 9:1177-1179 for reasons of record and herein below in the response to arguments.

Claims 9 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Entrez* Nucleotide sequence, Accession No. AF061836 (gi:3126875), published 9 May 1998 (hereinafter, AF061836) for reasons of record and herein below in the response to arguments.

Response to Arguments

Claim Rejections - 35 USC § 112

Claim 10 was rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the full scope of variants encompassed by the claim.

In response to the *prima facie* case of record, Applicant has amended the claim such that the variants are limited to having the functional activity of binding βTrCP or RasSF1. Applicant argues that the description of the variants and methods of obtaining such variants are set forth in the specification.

This argument has been fully considered but is not deemed persuasive. First, the amendment and remarks do not address the statements regarding descriptive support for naturally occurring allelic variants (paragraph bridging pages 4-5 of the 22 October Office Action). Furthermore, the teachings from the specification cited by applicant are merely a general description of protein mutagenesis and provide no structural basis for the functional properties recited in the claim. Given the teachings of the specification, the skilled artisan would not be able to distinguish variants of SEQ ID NO: 1 or 3 encoding a protein having the function of binding βTrCP or RasSF1 from variants of SEQ ID NO: 1 or 3 that do not have that function. Clearly, therefore, the specification fails to disclose the relevant identifying characteristics of the claimed invention.

With regard to a description of a method for obtaining the claimed invention, an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property (*i.e.*, it encodes a polypeptide that binds βTrCP or RasSF1) because disclosure of no more than that, as in the

instant case, is simply a wish to know the identity of any DNA with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all DNA's that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, claim 10 stands rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description.

Claims 13, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

In the previous Office Action, it was established that although the specification does not explicitly state that the claimed pharmaceutical composition is to be used for gene therapy, the only utility asserted in the specification for a pharmaceutical composition comprising a genetically modified host cell is *ex vivo* gene therapy (see paragraph 0163). Likewise, the specification does not contemplate a use for the pharmaceutical composition comprising a vector consisting as set forth in claim 20 other than gene therapy. The rejection concludes that due to the art recognized unpredictability of gene therapy and the lack of guidance in the specification

or prior art with regard to how to use the claimed pharmaceutical composition, it would require undue experimentation to practice the invention.

In response, Applicant urges that the specification discloses more than one use for the compositions embraced by the pharmaceutical compositions such as to conduct the bait-prey interactions and to express the polynucleotides. Applicant seems to argue that these uses are not excluded from the claim by the recitation of "pharmaceutical" as evidenced by the Examiner's position that a culture medium qualifies as a "pharmaceutically acceptable carrier". Applicant argues that the claimed compositions are enabled by the specification even if gene therapy were not enabled since at least one use of the claimed compositions is enabled.

These arguments have been fully considered but are not deemed persuasive. Applicant appears to be arguing that a composition limited to being a pharmaceutical is not limited to pharmaceutical use. However, MPEP 2164.01(c) states: "When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991)". Thus, when a composition is limited to being a pharmaceutical, the specification must provide an enabled pharmaceutical use for the composition.

The Examiner's position with respect to enablement for the claimed pharmaceutical compositions is not inconsistent with the rejection of the claims under 35 U.S.C. §102, because anticipatory art need not teach how to use the composition. MPEP 2122 states: "In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but *no utility need be disclosed by the reference. In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)" (emphasis added).

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole. Therefore, the claims are rejected under 35 U.S.C. §112, first paragraph, as lacking enablement.

Claim Rejections - 35 USC § 102

Claims 6, 9-11, 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cenciarelli *et al.* (1999) *Curr. Biol.* 9:1177-1179 for reasons of record and herein below in the response to arguments.

As described in the previous Office Action, Cenciarelli *et al.* teaches a polynucleotide comprising the sequence set forth as SEQ ID NO: 1, and a vector and host cell comprising said polynucleotide, which anticipate the limitations of claims 6, 9-11 and 13. Furthermore, the skilled artisan would understand that the vector of Cenciarelli *et al.* would be comprised in a buffer that meets the limitations of "pharmaceutically acceptable carrier" as they are understood based on the discussion at paragraph [0130]. Thus, the teachings of Cenciarelli *et al.* also anticipate the composition of claim 20.

In response to the *prima facie* case of record, Applicant has amended the claims such that they are limited to consisting essentially of SEQ ID NO: 1, and argues that the limitation serves to exclude nucleotide sequences more than three times the size of SEQ ID NO: 1. This argument is not deemed persuasive because for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." Applicant has cited no definition of the basic and novel characteristics of SEQ

ID NO: 1 that would exclude a nucleotide sequence more than three times the size of SEQ ID NO: 1, which comprises SEQ ID NO: 1, from the scope of the claims.

With regard to claims 9 and 10, Applicant states, "Cenciarelli's sequence is most certainly not a fragment or a variant of SEQ ID NO: 1." This argument has been fully considered but is not deemed persuasive. With regard to a fragment, the claim is actually directed to a nucleic acid "*comprising* a fragment of the sequence designated as SEQ ID NOS: 1 or 3". Any nucleic acid that "comprises" SEQ ID NO: 1 also comprises all possible fragments of that sequence. The transition "comprising" is open to all sequences and does not exclude the sequence comprised with the fragment of SEQ ID NO: 1 from being a portion of SEQ ID NO: 1 as well.

With regard to "variants", in paragraph [0076], the specification indicates that "additions" are within the scope of variants. As pointed out by Applicant, the sequence disclosed by Cenciarelli *et al.* comprises additions to SEQ ID NO: 1. Thus, Cenciarelli *et al.* anticipates the instant claimed variants.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole. Therefore, the claims are rejected as anticipated by Cenciarelli *et al.*

Claims 9 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Entrez* Nucleotide sequence, Accession No. AF061836 (gi:3126875), published 9 May 1998 (hereinafter, AF061836) for reasons of record and herein below in the response to arguments.

The previous Office Action states, "AF061836 discloses a nucleic acid comprising a sequence that is 98.2% identical to the instant SEQ ID NO: 3 over its full length. Thus, AF061836 anticipates the fragment of claim 9 and the variant of claim 10" (page 13).

In response, while acknowledging that AF061836 is 98.2% identical to SEQ ID NO: 3, Applicant argues that AF061836 does not disclose any fragment of SEQ ID NO: 3, nor does it encode a polypeptide that binds to βTrCP or RasSF1.

These arguments have been fully considered but are not deemed persuasive. For reasons discussed above, any nucleic acid that "comprises" SEQ ID NO: 3 also comprises all possible fragments of that sequence. With regard to Applicant's assertion that the nucleic acid disclosed in AF061836 does not encode a polypeptide that binds βTrCP, there is no evidence of record that this is true. In fact, AF061836 identifies a coding sequence at nucleotides 142-954, which appears to be 100% identical to the coding sequence of the instant SEQ ID NO: 3.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole. Therefore, the claims stand rejected under 35 U.S.C. §102(b) as anticipated by AF061836.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 17, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The MPEP states, "[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." (MPEP § 2163.06). The MPEP further states, "[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed…If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application" (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

Newly added claim 16 is directed to a vector comprising both SEQ ID NOS: 1 and 3, claim 17 is directed to a host cell comprising the vector of claim 16, and claims 19 and 20 are directed to compositions comprising the host cell and vector. In support of the claims, Applicant cites pages 16 and 17 of the specification. However, the teachings cited merely describe various

vectors that might be used to express SEQ ID NO: 1 and 3. The Examiner can find no explicit or implicit teaching of a vector comprising both SEQ ID NO: 1 and 3 in the cited teachings or anywhere else in the specification. Therefore, absent evidence to the contrary, the limitations of the claims are newly added to the disclosure and, thus, constitute new matter.

Claims 2, 6, 9-11, 13 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Although claims 2, 6 and 9-11 were not previously rejected as lacking enablement, upon further consideration it is clear that the teachings fail to enable any of the claims for reasons previously set forth regarding enablement for pharmaceutical compositions and reasons set forth herein below.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and Breadth of the claims: The claims are directed to nucleic acids, and compositions comprising nucleic acids encoding β-TrCP protein and RasSF1, which are demonstrated by *in vitro* assays to interact with one another. With regard to using the claimed invention, the specification teaches that the nucleic acids can be used in assays to screen for agents that modulate the interaction, which, in turn, can be used as a pharmaceutical for preventing or treating tumors (see especially paragraphs [0017], [0024], [0131], [0139], [0155]), as well as the direct administration of the nucleic acids and compositions as gene therapy (*Id.*). As enablement for the latter utility has been discussed in the previous Office Action and herein above, the present discussion will focus on enablement for the screening assays and the agents identified thereby. First, Applicant is reminded that the enabling disclosure for a method of identifying an agent having a specific activity must teach the skilled artisan how to use the agent identified by the method without undue experimentation.

State of the prior art and level of predictability in the art: The specification cites Dammann *et al.* (2000) *Nat. Genet.* 25 : 315-319 and Vos *et al.* (2000) *J. Biol. Chem.* 275: 35669-35672 (made of record in the IDS filed 1 July 2002) as teaching that RasSF1A and RasSF1C are absent in tumor cell lines and that ectopic expression of RasSF1A inhibits the tumor-forming potential in nude mice of such cells. The specification asserts that βTrCP is a protein implicated in the regulation of the degradation of proteins phosphorylated upon two serine residues present in the motif DSGXXS such as IκB and β-catenin. The art is silent, however, with regard to the interaction of RasSF1 with βTrCP and the relevance of this interaction to cancer and tumorigenesis.

It has been recognized in the art for many years that "cancer" is a constellation of diseases having disparate molecular etiologies, wherein therapeutics effective in treating one type of cancer are not effective in treating many other types of cancer (see Salmon *et al.* (1995) *Cancer Chemotherapy,* In Basic & Clinical Pharmacology, sixth edition, (B. Katzung, ed.) Appleton & Lange, Norwalk, CN, pp. 823-857). Thus, the therapeutic application of an agent to the treatment of cancer requires the identification of cancers that respond to the agent. In the instant case, the skilled artisan is fully dependent upon the teachings of the specification provide guidance as to the to the manner and process of treating cancer using the agents identified by the method, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected use the invention as asserted in the specification.

Amount of direction provided by the inventor and existence of working examples: As stated in the previous Office Action, the teachings in the specification provide that βTrCP interacts with RASSF1 as evidenced by yeast two-hybrid analysis (see especially Example 6, beginning on page 37) and coimmunoprecipitation (see especially Example 8, beginning on page 40). The specification also provides that inhibition of RasSF1 expression by RNAi results in decreased β-catenin expression, while overexpression of RasSF1C results in an increase in β-catenin expression (see especially Example 12, beginning on page 47). The specification concludes, "[the] interaction of RasSF1 with βTrCP could influence the activity of RasSF1 and its tumor suppressive functions in lung, breast and ovarian tumors. In particular the precise mapping of the interaction domains on both proteins could be used to modulate the function of

RasSF1 in tumorigenesis in breast, lung, and ovarian tumors in which inactivation of RasSF1 has been associated with the cancer process" (page 48).

However, Damman *et al.* (*supra*) identify RasSF1A as a tumor suppressor and present data indicating that RasSF1A is not present in breast, lung and ovarian tumors (see especially Figure 3 and the first full paragraph on page 318 of Dammann *et al.*). Given that it is the absence of RasSF1A that the art recognizes as linked to tumorigenesis in some breast, lung and ovarian tumors, the skilled artisan would not expect a compound that modulates a complex of RasSF1A and βTrCP, which would also be absent, to affect the cancer phenotype in these cells. Applicant's assertion that the interaction of RasSF1 with βTrCP could influence the activity of RasSF1 and its tumor suppressive functions in lung, breast and ovarian tumors is merely speculation, and there is no evidence that the complex suggested in the specification as the target of the therapeutics has any determinative role in the cancer phenotype.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the relative level of skill in the art is high, the skilled artisan would not know how to use the claimed invention without first engaging in undue experimentation. The specification discloses that RasSF1 interacts with βTrCP and, based on teachings in the art showing that RasSF1A is a tumor suppressor that is inactive in some lung, breast and ovarian tumors, teaches that the skilled artisan can use nucleic acids encoding RasSF1 and βTrCP to identify agents that modulates the complex, which agents can be used to treat breast, lung, and ovarian tumors. However, there is no evidence of record to indicate that the complex of RasSF1 and βTrCP is in any way linked to any type of cancer, let alone a target for therapeutic intervention. Thus, one of ordinary skill in the art seeking to use the claimed invention as

asserted in the specification would have to establish by empirical experimentation which, if any, cancers could be treated using agents identified as modulating the RasSF1/βTrCP interaction. Given the diversity of cancers and the absence of evidence to indicate the RasSF1/βTrCP complex is a determinant in any cancer, using the invention according to the teachings of the specification would clearly require undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite in reciting "a vector consisting essentially of SEQ ID NO: 1". The phrase reads as though the essential elements of the vector are comprised within SEQ ID NO: 1; however, SEQ ID NO: 1 does not comprise any vector elements. It would seem that Applicant intends that the composition comprise a vector comprising a nucleic acid consisting essentially of SEQ ID NO: 1. If so, amending the claim accordingly would be remedial.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

DAVID GUZO
PRIMARY EXAMINER